03-12-03

**PATENT** IN THE UNITED STATES PATENT AND TRADEMARK OFFICE MAR 1 1 2003 (Case No. 98,723-E1) plication of: Juan Saus Art Unit: 1645 Serial No.: 10/008,721 Examiner: To be assigned Filed: December 7, 2001 For: **TNF-Inducible Promoters And Methods** For Using Commissioner for Patents Washington, D.C. 20231 TRANSMITTAL LETTER Sir: 1. We are transmitting herewith the attached papers for the above-iden application: ☐ Information Disclosure Statement (9 sheets); ☐ Information Disclosure Statement Form 1449 (4 sheets); Copy of International Search Report from PCT App. No. PCT/EP01/14412 (6 sheets); 51 cited References Return Receipt Postcard With respect to fees: No fee is due. Please charge the total filing fee of \$0.00 to our Deposit Account No. 13-2490. A duplicate copy of this sheet is enclosed. CERTIFICATE OF MAILING BY "EXPRESS MAIL" UNDER 37 CFR § 1.10: The

undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as "Express Mail Post Office to Addressee" in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this day of March, 2003. Express Mail No. EV214228005US.

By:

Registration No. 42,636





# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 98,723-E1)

In the Appli	cation of: Saus, J	)
		) Art Unit: 1645
Serial No.	10/008721	) Examiner: To be assigned
Filed:	December 7, 2001	)
Title: TNF-1	Inducible Promoters and Methods for Using	)

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# INFORMATION DISCLOSURE STATEMENT

MAR 1 4 2003

Commissioner for Patents Washington, D.C. 20231

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Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. However, the references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative relevance between references, whether cited in this or prior statements. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

	This I	nformation Disclosure Statement is being filed:	
	date o	three months of the filing date of a national applicate function of entry into the national stage as set forth in 37 C. ation; or before the mailing date of a first Office A (b)	F.R. § 1.491 in an international
	nation mailin Action	three months of the filing date of a national applicate all stage as set forth in 37 C.F.R. § 1.491 in an interrug date of a first Office Action on the merits, but be a under 37 C.F.R. § 1.113 or a Notice of Allow hever occurs first), and includes (37 C.F.R. § 1.97 (context)	national application; or after the efore the mailing date of a Final vance under 37 C.F.R. § 1.311
		the Certification under 37 C.F.R. § 1.97(e) (see "C	Certification" below)
		OR	
		the fee of \$180 set forth in 37 C.F.R. § 1.17(p) (see	e "Fees" below).
	1.311 issue below Payme Inform	a Final Action under 37 C.F.R. § 1.113 or a Notice of (whichever occurs first), but before, or simultanesfee, and includes the Certification under 37 C.F.R. ), and the Petition Fee set forth in 37 C.F.R. § 1.17 ent of Fees" below). Applicants hereby petitionation Disclosure Statement submitted herewith an imination of the subject patent application.	ously with, the payment of the R. § 1.97(e) (see "Certification" (i) (see "Fees" and "Method of ions for consideration of the
CERT	IFICAT	CION	
	Inform office	andersigned hereby certifies that each item of nation Disclosure Statement was cited in a communing a counterpart foreign patent application not more of the Information Disclosure Statement.	unication from a foreign patent
	Inform office signing design	andersigned hereby certifies that no item of nation Disclosure Statement was cited in a communing a counterpart foreign patent application or, to gethe certification after making reasonable inquiry ated in 37 C.F.R. § 1.56(c) more than three monation Disclosure Statement.	inication from a foreign patent the knowledge of the person, was known to any individual
		n, Hulbert & Berghoff e Suite 3700	U.S. Serial No.:

FEES  No fee is owed by the applicant(s).  The IDS Fee of \$180.00 under 37 C.F.R.	§ 1.17(p) is enclosed herewith.
METHOD OF PAYMENT OF FEES  Attached is a check in the amount of \$180. Charge Deposit Account No. 13-2490 in the communication is enclosed for that purpos	ne amount of \$ . (A duplicate copy of this
Please charge any underpayment or credit communication to Deposit Account No. 13-2490 enclosed for this purpose.	
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Date: 3/11/0/3	David 9. Harper Registration No. 42,636
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McDonnell, Boehnen, Hulbert & Berghoff 300 S. Wacker Drive, Suite 3200 Chicago, IL 60606 312-913-0001	U.S. Serial No.: Filing Date:

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## II. Other Documents

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- 3. Beck et al. (1992) DNA sequence analysis of 66 kb of the human MHC class II region encoding a cluster of genes for antigen processing. Database Accession Number X66401.
- 4. Brenner, V., Nyakatura, G., Rosenthal, A. and Platzer, M. (1997) Genomic organization of two novel genes on human Xq28:Compact head to head arrangement of IDHγ and TRAPδ is conserved in rat and mouse. *Genomics* 44, 8-14.
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- 7. Casciola-Rosen, L.A., Anhalt, G. and Rosen, A. (1994) Autoantigens targeted in systemic lupus erythematosus are clustered in two populations of surface structures on apoptotic keratinocytes. J. Exp. Med. 179, 1317-1330.
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#### III. Discussion

In accordance with MPEP Sections 609 and 707.05(b), it is requested the documents cited be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

U.S. Serial No.: \_\_\_\_\_\_\_

Respectfully Submitted,

By:

David Harper
Reg. No. 42,636
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300 South Wacker Drive
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Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

#### **FOREIGN PATENT DOCUMENTS**

						Trans	slation
	Document Number	Date	Country	Class	Subclass	Yes	No
1.	WO 00/50607	Aug. 31, 2000	PCT				

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

2.	Aggarwal et al. (2001) TNFα in Cytokine Reference. A compedium of cytokines and other mediators of host defense Oppenheim, J.J eds. Vol. 1 (Academic Press Ltd., London), pp 413-447.
3.	Beck et al. (1992) DNA sequence analysis of 66 kb of the human MHC class II region encoding a cluster of genes for antigen processing. Database Accession Number X66401
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8.	Casciola-Rosen, L., & Rosen, A. (1997) Ultraviolet light-induced keratinocyte apoptosis: a potential mechanism for the induction of skin lesions and autoantibody production in LE.Lupus 6, 175-180.
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10	Echtenacher B, Falk W, Mannel DA and Krammer PH (1990) Requirement of endogenous Tumor Necrosis Factor/Cachectin for recovery from experimental peritonitis. J. Immunol. 145, 3762-3766.
11	Felmann, M., Bondeson, J., Brennan, F.M., Foxwell, B.M., and Maini, RN.(1999). The rationale for the

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MAR 1 1 2003	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).
PADEMARK DEUS	current boom in anti-TNF $\alpha$ treatment. Is there an effective means to define therapeutic targets for drugs that provide all the benefits of anti-TNF $\alpha$ and minimise hazards? Ann. Rheum. Dis. 58 Suppl1, I27-31.
12.	Gavalas, A. and Zalkin, H. (1995) Analysis of the chicken <i>GPAT/AIRC</i> bi-directional promoter for <i>de novo</i> purine nucleotide synthesis. J. Biol. Chem. <b>270</b> , 2403-2410.
13.	and mouse homologs of E. coli DinB (DNA polymerase IV), members of the UmuC Din Surer Amily
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28.

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E TI	AP	29.	Ohashi, E., Bebenek, K., Matsuda, T., Feaver, W.J., Gerlach, V.L., Friedberg, E.C., Ohmori, H. and
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		30.	Oohashi, T., Ueki, Y., Sugimoto, M. and Ninomiya, Y.(1995). Isolation and structure of the COL4A6
			gene encoding the human $\alpha 6$ (IV) collagen chain and comparison with other type IV collagen genes. J.
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1111	ti-e	31.	Polos, J.L., Santiago, B., Galindo, M., Carreira, P.E., Ballestin, C. and Gomez-Reino, J.J. (1999) Keratinocyte apoptosis and p53 expression in cutaneous lupus and dermatomyositis. J. Pathol. 188, 63-
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